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TITLE OF INVENTION (280 characters max)

NEEDLEFREE CONNECTOR AND METHOD OF MAKING SAME

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PROVISIONAL APPLICATION FILING ONLY

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PROVISIONAL APPLICATION FOR UNITED STATES LETTERS PATENT

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NEEDLEFREE CONNECTOR AND METHOD OF MAKING SAME

BACKGROUND

This invention relates to needlefree connectors for use with liquid flow and administrative apparatus for medical purposes, and methods of making needlefree connectors.

The use of hypodermic needles to inject or withdraw fluids in medical application had been standard practice up until a few years ago. Even where a patient already had an IV tubing set connected to a vein, hypodermic needles were frequently used to inject fluids into the IV tubing. Often a "Y connector" with a septum was provided in the tubing set for this very purpose. The needle was used to puncture the septum to administer the drug or other fluid, and the septum then sufficiently sealed the opening to prevent leakage, and prevent airborne bacteria from entering the system. Septums are also common on drug vials, where the needle is inserted to withdraw a quantity of the drug.

The widespread use of hypodermic needles lead to numerous needle-stick accidents. These were not only painful, but if the needle is contaminated, could cause serious disease or complications in the needle-stick victim. There has been a desire for needlefree medical systems, where a fluid can be injected or aspirated without the use of a needle, but while maintaining an aseptic leak-free system.

Numerous devices have been developed to achieve this goal. Many of those devices have been disclosed in the patent literature. One early such device is disclosed in U.S. Patent No. 5,360,413. The different embodiments of the needleless access device disclosed in the '413 patent have proven to be influential in the design of subsequent needlefree connectors. Many of the concepts have been used in other devices. The wiper seal to seal the inlet channel against airborne bacteria and the piston head that can be easily swabbed prior to actuation are two of the more significant features.

Even with all the work and development that has transpired over the years in this area, there is still need for improvement, particularly with respect to better

performance, such as greater flow rate and reduced trapped drug and fluid after flushing, and lower cost. The preferred embodiments disclosed in the '413 patent are assembled from four or five components, depending on the design. Even though the parts can be mass produced, the product cost is dependent on the number of individual components that have to be made, and then assembled. Most needlefree connectors commonly available contain at least three parts. Many prior needlefree connectors also have internal configurations that allow fluid to be trapped in the device even after flushing. Also, many prior devices are fairly large and therefore have a higher material cost and internal volume.

The desire to reduce the number of parts that must be assembled, however, cannot override the more important fact that the product must meet several critical design features. Thus, there is a real need for needlefree connector products that can be made at a lower cost, but still meet the end user's specifications.

BRIEF SUMMARY

The present invention includes needlefree connectors that are lower in cost and have low hold-up volumes. Preferred connectors may be assembled from only two parts, yet still provide at least as good, and in many ways superior, performance compared to many prior art devices.

In a first aspect, the invention is a needlefree connector comprising a housing having an inlet and an inlet channel; and a combination outlet, biasing and piston member having a piston section moveable between a closed position in which the piston section is in the inlet channel and an open position in which the piston section is inside the housing below the inlet channel but allows fluid to flow through the inlet channel, a biasing section connected to the piston section that normally biases the piston section into the inlet channel; and an outlet section interlocked to the biasing section and having an outlet fitting in fluid communication with the inside of the housing, wherein the piston section, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing to make the needlefree connector.

In a second aspect, the invention is a needlefree connector comprising a housing and a flow control member, the flow control member comprising thermoplastic material and thermosetting material overmolded to the thermoplastic material.

In a third aspect, the invention is a needlefree connector comprising: a housing and a flow control member, the flow control member comprising a thermoplastic outlet section and a resilient material overmolded onto the thermoplastic material.

In a fourth aspect, the invention is a flow control member for use in a needlefree connector, the flow control member comprising an outlet section formed of thermoplastic material; and a combined biasing section and piston section formed from resilient material, the biasing section being molded onto the outlet section.

In a fifth aspect, the invention is a needlefree connector comprising a housing having an inlet, a base, and a main body portion having a generally cylindrical inside surface between the inlet and the base; a valve member actuatable between an open position and a closed position, wherein in the closed position the valve member prevents flow between the inlet and the outlet; a central body within the main body portion of the housing, the central body having a helical shape on its outer surface, the central body fitting against the inside of the cylindrical surface when the valve member is in its open position; the helical shape thus defining a helical flow path through the main body portion of the housing when the valve member is in an open position.

In a sixth aspect, the invention is a needlefree connector comprising a housing having a round inlet, a tapered inlet channel that narrows inwardly from the inlet, a main body portion, and a base opposite the inlet; a piston member inside the housing; and a biasing member inside the housing normally biasing the piston member to close the inlet; wherein the piston member comprises a resilient material with a top having a generally elliptical shape and an opening that is closed when the top of the piston is forced into the round inlet opening but which allows flow through the opening to the outside of the piston member when the

piston member is forced downwardly against the biasing force and out of the tapered inlet channel.

In a seventh aspect, the invention is a method of making a needlefree connector comprising forming a housing having an inlet and a base; forming a flow control member by molding thermoplastic material to form an outlet member and molding resilient material onto the outlet member, the resilient material forming a piston section and a biasing section; inserting the flow control member into the housing such that the piston section is adjacent to the inlet; and securing the outlet member into the base of the housing.

In an eighth aspect, the invention is a method of making a needlefree connector comprising providing a first part comprising a monolithically formed housing; providing a second part comprising a combination outlet section, biasing section and piston section; constructing the needlefree connector by securing the second part within the first part, the connector being made only from the first and second parts.

The preferred needlefree connector, being made with only two parts, can be assembled at a low cost. By using a two-shot molding process, a combination part can be made that includes several functional sections: a piston section, a biasing section and an outlet section. The unique manufacturing methods of the present invention allow this part to be made at a relatively low cost, yet the preferred needlefree connector has functional characteristics that are highly desirable. In addition, quality control is improved since only two parts have to be assembled. These and other advantages and features of the invention will be best understood in light of the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a first embodiment of a needlefree connector of the present invention;

Figure 2 is a view of the connector of Figure 1 from a different perspective;

Figure 3 is an exploded view of the combination outlet, biasing and piston member, also referred to as a flow control member, of the connector of Figure 1;

Figure 4 is an exploded perspective view of the connector of Figure 1;

Figure 5 is a longitudinal cross-sectional view of the housing used in the connector of Figure 1;

Figure 6 is a cross-sectional view taken along line 6-6 of Figure 4;

Figure 7 is a cross-sectional view taken along line 7-7 of Figure 1;

Figure 8 is a partial cross-sectional view taken along line 8-8 of Figure 1;

Figure 8A is a partial cross-sectional view of the connector of Figure 1 shown in its open, activated position;

Figure 9 is a perspective view of a second embodiment of combined biasing and piston sections of a flow control member of the present invention;

Figure 10 is a cross-sectional view of a third embodiment of a needlefree connector of the present invention in its open, activated position;

Figure 11 is a cross-sectional view of a fourth embodiment of a needlefree connector of the present invention;

Figure 11A is a cross-sectional view taken along line 11A-11A Figure 11;

Figure 12 is a cross-sectional view of a fifth embodiment of a needlefree connector of the present invention;

Figure 13 is a cross-sectional view of a sixth embodiment of a needlefree connector of the present invention;

Figure 14 is a partial cross-sectional view of an I.V. bag using the needlefree connector of Figure 1 as a bag port;

Figure 15 is a cross-sectional view of a seventh embodiment of a flow control member of the present invention;

Figure 16 is a cross-sectional view of an eighth embodiment of a flow control member of the present invention;

Figure 17 is a cross-sectional view of a ninth embodiment of a flow control member of the present invention;

Figure 18 is a cross-sectional view of a tenth embodiment of a flow control member of the present invention;

Figure 19 is a cross-sectional view of an eleventh embodiment of a flow control member of the present invention;

Figure 20 is a cross-sectional view of a twelfth embodiment of a flow control member of the present invention;

Figure 21 is a cross-sectional view of a thirteenth embodiment of a needlefree connector of the present invention;

Figure 22 is a cross-sectional view of thc mold tool used to form the outlet section of the connector of Figure 1;

Figure 23 is a cross-sectional view of the mold tool used to overmold the combined biasing section and piston section of the connector of Figure 1;

Figure 23A is a partial enlarged cross-sectional view of an alternate embodiment of the mold tool used to overmold an alternate combined biasing section and piston section of the connector of Figure 1;

Figure 24 is an elevational schematic view of a horizontal molding press that can be used to make needlefree connectors of the present invention;

Figure 24A is a schematic top view of one embodiment of the operation of the central portion of the press of Figure 24;

Figure 24B is a schematic top view of a second embodiment of the operation of the central portion of the press of Figure 24;

Figure 25 is a schematic view of a manufacturing cell that can be used to makc conncctors of the present invention using two vertical molding presses;

Figure 26 is a perspective view of a fourteenth embodiment of combined biasing and piston sections of a flow control member of the present invention;

Figure 27 is a cross-sectional view of a needlefree connector using the flow control member with the combined biasing and piston sections of Figure 26;

Figure 28 is a cross-sectional view of a first Y-shape needlefree connector of the present invention;

Figure 29 is a cross-sectional view of a second Y-shape needlefree connector of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

The first preferred embodiment of the needlefree connector 10 of the present invention is shown in Figures 1-9. As noted above, the connector 10 is assembled from a first part, which comprises a housing 20, and a second part 40, which comprises a combination outlet, biasing and piston member. This second part acts as a flow control member. Together the two parts 20 and 40 form the complete needlefree connector 10. As will be explained in detail, the flow control member 40 provides several functional parts to the connector 10. It is preferably made in a two shot molding process. Since one molding press is needed for the two shot molding, the cost for this part is less than if it were made from two separate molding operations. Furthermore, since the connector 10 is made from only these two parts, it can be assembled at a lower cost than if it were assembled from three or more parts.

The housing 20 is preferably monolithically formed, such as by an injection molding process. As best seen in Figure 4 and 5, the housing has a round inlet 22 leading into a tapered inlet channel 24 that narrows inwardly from the inlet 22. The inlet 22 and inlet channel 24 preferably form a female luer taper for engaging with a syringe tip 18 (Figure 9) having a standard male luer taper. The housing also includes a base 26 with threads 36 for forming a luer lock.

The housing 20 has a main body portion 28 with a generally smooth cylindrical inside wall surface 29 between the inlet 22 and the base 26. The housing also includes an internal sealing surface 30. The outside of the upper portion 32 of the housing 20 also includes threads 38 for a luer lock.

The combination outlet, biasing and piston member 40 can be thought of as having three sections: a piston section 50, a biasing section 60 and an outlet section 70. The piston section 50 provides a piston member with a wiper seal 52 and a valve member 54. The piston section is movable between a closed position, in which the piston section is in the inlet channel 24 (Figure 8), and an open position, in which the piston section is inside the housing below the inlet channel, but allows fluid to flow through the inlet channel (Figure 8A). The wiper seal 52

is dimensioned so that it ensures sealing in the inlet channel acting to maintain sterility against bacterial contamination when the piston section is in its closed position, and to wipe the inlet channel so as to leave the wiped area in a clean state. In the closed position, the valve member 54 of the piston section seals against the internal sealing surface 30 of the housing, thus preventing flow between the inlet and the outlet. This is primarily used to prevent backflow through the connector when the piston section is in the closed position. The biasing section preferably provides sufficient force to keep the valve member 54 closed even if a vacuum is drawn on the outlet.

The biasing section 60 is connected to the piston section 50 and normally biases the piston section into the inlet channel 24. The biasing section 60 has a central hollow portion 62 (Figure 6), which allows the wall 64 of the biasing section 60 to collapse. The biasing section 60 also provides a central body having a helical shape on its outer surface, such as a helical groove 64 on the outside thereof. Otherwise, in a collapsed state, the central body fits against the inside of the cylindrical surface 29 of the housing. The helical groove 64 thus defines a helical flow path or channel through the main body portion 28 of the housing 20. When the connector is in its open position (Figure 8A) the helical flow channel formed in the outer surface of the biasing section 60, around its center portion, preferably has a cross-sectional width 66 of about 0.02 inches. Preferably the biasing section 60 and piston section 50 are formed as one monolithic piece.

The outlet section 70 is connected to the biasing section 60, preferably by having the biasing section 60 overmolded to the outlet section. The outlet section provides an outlet fitting 72, preferably having a male luer taper. The outlet fitting 72 is in fluid communication with the inside of the housing. The outlet section includes a flange 74 that fits in a recess 37 in the housing 20 (Figure 5). Thus, the outlet section 70 forms a closure to the housing 20, thus directing flow through the housing to pass through the outlet fitting 72. Fluid can enter the outlet fitting through openings 76 formed near the top of the outlet section. These openings are in fluid communication with the central flow channel 78 through the center of the outlet section 70. Preferably the housing 20 includes an internally threaded

section 35 (Figure 5) adjacent the connection between the biasing section and the outlet section so that fluid traveling down the helical flow channel 64 can make it past the connection between the biasing section and the outlet section and into openings 76.

The biasing section and piston section are preferable made of resilient material, and more preferably a resilient thermosetting material such as silicone, whereas the outlet section is preferably made of thermoplastic. In the past, these two materials have not been commonly molded together. Silicone does not generally adhere to thermoplastic. However, a thermosetting material is desirable for the biasing section because it needs to be resilient, and, more importantly, not "cold flow". Most thermoplastics, including thermoplastic elastomers, experience cold flow, meaning that they permanently deform when left under pressure. If the biasing section were made of a material that experienced cold flow, after a period of storage in an assembled state, the biasing member would no longer continue to urge the piston section 50, and valve member 54 in particular, into the inlet channel and against the sealing surface 30.

The wiper seal 52 also should maintain its shape over time. Thermoplastic elastomers that are currently commercially available would provide the resiliency needed, but would undergo cold flow if the needlefree connector 10 were assembled and placed in storage awaiting distribution and use. However, in the future thermoplastic elastomers may be developed which would not have a detrimental degree of cold flow.

The top of the preferred piston is either flush with, or more preferably, extends out of the inlet 22 of the housing so that it can be aseptically swabbed. The piston section 50 of the preferred embodiment also provides a unique inlet flow path that is made possible because a resilient material is used. The top of the piston section has a generally elliptical shape in its unconfined form and a wedged shaped opening 56 that is closed when the top of the piston section 50 is forced into the round inlet opening. When the piston member is forced downwardly against the biasing force and out of the tapered inlet channel, the normally generally elliptically top portion with wedged shaped opening 56 returns to its

underformed shape as the syring tip forces it down out of the inlet channel to a point in the housing having a wider cross section. The opening 56 extends radially from the longitudinal centerline of the piston member. However, the opening 56 does not interconnect with the hollow central portion 62 of the biasing section. Thus, when the connector is accuated, the flow out of the syring tip passes through the opening 56 and out to the side of the piston member into an area of reduced diameter above the valve member 54 portion of the piston section 50. From here it can pass down the helical flow channel 64, through the openings 76 and out the central flow channel 78.

Rather than have a wedge shaped opening 56, other opening shapes may be used. A V-shaped groove extending across the minor axis of the elliptical shape of the piston top will have the same ability to close up when forced upwardly into the inlet channel, but spring back open when depressed, and allow fluid flow out both sides of the groove. Such a V-shaped groove is shown in the embodiments of Figures 15-17.

As noted above, the connector 10 is preferably made by providing a first part comprising the monolithically formed housing 20, providing a second part comprising the combination outlet section, biasing section and piston section, and constructing the needlefree connector 10 by securing the second part within the first part. Preferably the housing 20 is made of a thermoplastic material that allows the flange 74 on the outlet section to be sonically welded into the recess 37 in the base of the housing 20. In this manner the connector can be assembled from only two parts. Thus, in the preferred embodiment of the invention, piston section 50, biasing section 60 and outlet section 70 are connected together such that they can be handled as one piece when assembled with the housing 20 to make the needlefree connector 10. Hence, the combination outlet, biasing and piston member exists as a single part before the needlefree connector is assembled.

The preferred combination outlet, biasing and piston member 40, which constitutes one variety of a flow control member, is made by first injection molding thermoplastic material to form the outlet section 70. Figure 22 shows a mold that can be used for this purpose. The mold has a base section 80 and a first

top section 82. The central flow channel 78 is formed by a center core pin 84. The core pin 84 has an extension making it longer than needed, as will be explained later. The openings 76 are formed by side action pins 86, as is well known in thc art of thcrmoplastic molding. Hot, molten thermoplastic material is injected through port 88 to form the outlet section 70. After the outlet section 70 has solidified, the first top mold section 82 is removed. However, the outlet section is not ejected from the mold base 80, nor is the center core pin 84 removed. Instead, a second top section mold is put in place, as shown in Figure 23. This second top mold section is made of two halves, 90 and 92. Each mold half has an extension 94 that extends into one of the openings 76 to keep it open during the subsequent overmolding operation. Mold half 90 includes a port 96 through which resilient material is injected into the cavity. Mold half 92 includes a protrusion 98 that is used to form the wedge shaped opening 56 in the piston section 50. The extended part of the center core pin 84 now forms the hollow central portion of the biasing section 60. The helical flow channel is made by flights on the insides of the top mold halvcs (cither chemically or by solidifying from a molten state) 90 and 92.

In the preferred embodiment, the outlet section 70 interlocks with the biasing section 60. This can be either a chemical or physical interlocking. If the resilient material does not bond to the thermoplastic material, the junction between the outlet section 70 and biasing section 60 can be designed so that the biasing section is mechanically interlocked to the outlet section 70. This is most easily done by forming an undercut in the top of the outlet section 70 just above the openings 76, as shown in Figure 23A. However, first top mold 82 may then need to be made of two parts. It is important that mold base 80 be made of only one part so that there is no part line in the luer taper section 72 of the outlet section 70.

As used herein and in the claims, the term "overmolding" is used to refer to a process in which a first part is placed in a mold tool such that at least a portion of the surface of that part is exposed within the cavity of the mold tool. Thereafter material is introduced into the cavity to form an overmolded part having the shape of the cavity. The new material is in intimate contact with the exposed surface of

the first part within the cavity, and is thus overmolded onto the first part. The first part may be of a different or the same material as used to make the overmolded part. The overmold material may form a chemical or melt bond to the first part, but this is not always the case. As just discussed, the overmolded biasing section 60 may be mechanically interlocked to the outlet section 70.

In the preferred embodiment of the invention, the outlet section 70 is not removed from the mold base 80 until it has the biasing section 60 and piston section 50 connected to it. In this manner the combination part can be handled as one piece during the assembly process. This simplifies the assembly, and hence reduces the cost of the needlefree connector 10. In addition to overmolding, there are other ways to produce such a connected part using in-press assembly, meaning assembly of the combined part while still in the molding press. For example, the biasing and piston section could be molded with a different mold that did not have the outlet section already in it. Both the outlet section still in its base mold and the combined biasing and piston section still held by its mold could be brought together and joined, such as with an interference fit between the parts. The parts only need to be secured together to the extent that they remain together until inserted into a housing. The joint between the biasing section and outlet section need not prevent leakage because any leakage would be inside the housing and flow into the same path that fluid will flow anyway.

The outlet section 70 will typically be molded from a thermoplastic injected at a temperature of between about 300°F and about 800°F, and at a pressure of between about 500 psi and about 2000 psi. The mold base 80 will typically be cooled so as to maintain a temperature of between about 50°F and about 300°F when the thermoplastic material is injected. The precise temperatures and pressures will depend on the mold configuration and the thermoplastic used, as is well known in the art. The thermoplastic material will most likely be selected from the group consisting of polycarbonates, polysulfones, nylons and acrylics. When polysulfones are used, the injection temperature will typically be in the 700-800°F range. Polycarbonates, which are presently preferred, are injected at a

temperature of about 600°F. A particularly preferred thermoplastic is Lexan™ polycarbonate from GE Plastics.

The second top section mold halves 90 and 92 will typically be heated so as to cause the thermosetting material to cure. The themosctting material is preferably silicone rubber, which is made by mixing a silicone part A with a silicone part B. This mixing will most typically occur just before the material is injected into the cavity of the second top section mold. However, the materials may be premixed and stored until used as long as it is stored under conditions and for a duration that do not cause it to solidify. The material will typically be injected at a pressure of between about 100 psi and about 900 psi, and at a temperature of between about 50°F and about 100°F. The second top mold section will preferably be heated to a temperature of between about 250° and about 400°F when the mixture is injected. A preferred material is LIM607 from GE Silicone, a 70 durometer liquid injection moldable material.

A simple manufacturing cell 300 that could be used to mold the flow control member 40 on pilot scale is shown in Figure 25. The cell has two molding press stations 302 and 304, a holding station 306, and an off-loading station 308. Several multicavity mold bases 310, 312 and 314 are used, each identical and containing eight cavities of a design of the mold base section 80. At molding press station 302, thermoplastic is injected into the cavities of mold base 310 to form eight separate outlet sections 70. The mold top held in press station 302 has eight cavities of the top section 82. At the same time this operation occurs, mold base 312, which was previously in molding press section 302 and had the outlet sections 70 moldcd in it, is in molding press section 304, where thermosetting material is injected to form the biasing section 60 and piston section 50. Of course molding press section 304 carries an eight cavity mold, each with the mold halves 90 and 92 operational therein. At the same time that the two molding operations are going on in molding press stations 302 and 304, finished flow control members 40 are off-loaded at off-loading station 308 from mold base 314 which previously went through both molding press sections 302 and 304.

At the end of one cycle, when molding press sections 302 and 304 are open, the mold bases 310, 312 and 314 are moved in a counter clock-wise direction. Mold base 310 is first moved to holding station 306. Mold base 314 now empty, is moved from thc off-loading station 308 to the first molding press section 302. Mold base 312 is moved from molding press section 304 to off-loading station 308. Then mold base 310 can be moved from holding station 306 into the molding press section 304. The molding and off-loading operations are then repeated, and the cycle continues. One operation stationed at position 316 moves the mold bases 310, 312 and 314 to thcir ncxt location, while a second opcrator at position 318 off-loads the molded parts.

A preferred high-capacity manufacturing operation that may be used to mold the flow control member 40 uses a rotary turntable molding press 400, such as a Krauss Maffei brand rotary press, modified to use liquid inject moldable material on one side, as shown in Figure 24. The press 400 has a rotating center section 410, a left platen 412 used to mold thermoplastic matcrial and a right platen 414 used to mold thermosctting material. Platen 414 stays fixed, but center section 410 and left platen 412 are moveable along linear guiding rails on the machine bed. Double acting hydraulic cylinders 416 or other types of mechanical devices reciprocate to move the platen 412 and center section 410 from an open position as shown to a closed position in which the moveable portions are shifted to the right to close up the molds carried on the platens and center section 410. These cylinders also supply the needed clamp pressure for the injection molding operations. The center section 410 can be designed to carry either two or four multicavity mold bases 420, each cavity having the shape of mold base section 80 without injection port 88. Platen 412 carries the first mold top 424 with cavities of the shape of top section 82, modified to include a port to inject the thermoplastic. Platen 414 carries the second mold top 426 with cavities in the shape of mold halves 90 and 92. The center section 410 slides on a bed, and has means (not shown) to slide it back to the center position after a molding step.

A thermoplastic injection system 428 is connected to and travels with platen 412, so as to be able to inject molten thermoplastic through hot runners in

the mold top 424. The thermoplastic injection system 428 is conventional in design, with a heated barrel and a screw with flights to create the necessary injection pressure. On the right, stationary side the press 400 holds two tanks 430 and 432 which hold the two silicone part A and silicone part B, respectively. Metering pumps draw the liquid from the tanks and feed it through hoses 434 and 436 into a screw cylinder 438 where the two liquids are mixed. The screw cylinder also builds the pressure to inject the silicone through runners in a cold plate formed as part of second mold top 426. However, the rest of the mold top 426 is heated to provide conditions that will cure the silicone once it is mixed and injected.

The center section 410 includes energy circuits that allow the mold bases 420 to be cooled. For example, the mold bases may be left at about 40-60°F. The energy circuits also actuate moveable portions within the mold bases 420. Water is also used to cool the first mold top 424, to keep it at a temperature of about 100-130°F. The second mold top 426 is held a temperature of about 350-375°F.

The center section 410 includes a rotary table, to allow the center section to rotate between its various positions. If four mold bases 420 are used, as shown in Figure 24A, the mold bases rotates 90° at each step between a first molding station, where the thermoplastic is injected to form outlet sections 70, to a cooling station, to the second molding station where the silicone is overmolded, and finally to the off-loading station where the finished parts are ejected from the mold base 420.

Figure 24B shows an alternative arrangement where only two mold bases 420 are in place on center section 450. In this embodiment, the first molding and cooling operations both occur while the first mold base 420 is in the first station. Meanwhile, the second molding with silicone, followed by off-loading is occurring with the second mold base 420 in the second position. The center section 450 is rotated 180° between each operation.

The needlefree connector of the present invention may be made with different parts than those shown in Figures 1-8. For example, combined biasing and piston sections for a second embodiment of a flow control member are shown

in Figure 9. The biasing section 90 differs from biasing section 60 in several respects, most significantly in that it is not hollow. Rather, the biasing section 90 has a solid central portion with a helical shape on its outer surface. However, the central portion is reduced in its average outside diameter so that the cross-sectional area of solid resilient material is comparable to the cross-section of material in the biasing section 60 so that the biasing section 90 can still collapse. The helical shape of its surface has a steeper pitch than in biasing section 60. However, it cooperates with a housing (not shown) to define a helical flow path 94 when the valve member is open. The piston section 92 uses the same wedge shaped opening 96 as is used in piston section 50. The combined biasing section 90 and piston section 92 are preferably formed as one monolithic part, overmolded onto an outlet section (not shown) that may have the same configuration as outlet section 70. They are then inserted as a combined outlet, biasing and piston member into the housing just as with the connector 10. A syringe tip can be pushed down to compress the biasing member 90 just as in Figure 8A. The wedge shaped opening 96, which is closed when the piston 92 is in a round inlet of a housing, then opens up to allow fluid to travel downwardly into the housing and out of opening 98.

A third embodiment of a needlefree connector 100 is shown in Figure 10. The needlefree connector 100 is also constructed from two parts. A housing 102 has a shape very similar to housing 20 of needlefree connector 10, and the flow control member 104 is very similar to the flow control member 40. The primary difference is the shape of the opening 106 in the piston section. Whereas opening 56 was wedge shape, the opening 106 is more of a "U" shape that extends across the small diameter of the elliptical head. The opening 106 is closed when the biasing section forces the piston section into the inlet channel of the housing 102. However, as shown in Figure 10, when a syringe tip 18 is inserted and depresses the top of the piston, the resiliency of the piston causes the opening 106 to open up so that fluid can flow from the syringe tip and out through the side of the piston section and follow a helical flow path around the biasing section as in connector 10.

Just as with connector flow control member 40, the flow control member 104 has a thermoplastic outlet section 106 with thermosetting material, such as silicone, overmolded to it to form the biasing section and piston section.

A fourth embodiment of a needlefree connector 130 is shown in Figures 11 and 11A. The housing 132 used in this connector is similar to housing 112, including a horizontal sealing surface 133. The piston section 138 and the biasing section 140 both include openings 142 formed sideways through the resilient material. These allow the biasing section 140 to be compressed by a syringe tip forcing the piston section 138 downwardly. In the embodiment of Figure 11, the flow path is around the outside of the biasing section as with the previously described embodiments. However, the flow path does not have a helical shape. Rather flow channels 143 are formed in the side walls 144 of the housing 132. These flow channels connect to a circumferential flow channel 145. Openings 146 are formed in the outlet section 148, similar to openings 76 in outlet section 70. The openings 146 are adjacent to and in fluid communication with circumferential flow channel 145. Another feature of needlefree connector 130 is that it creates positive displacement when activated. In the embodiment of Figure 11, the outlet section 148 must be molded from a resilient thermoplastic in order for the portion of the mold tool that create voids 149 to be withdrawn after the outlet section is molded. In any event, again, the part can be made by a two shot molding process like the other embodiments. The voids 149 are open to the atmosphere out the bottom of the connector. Thus, air can be forced out the bottom when the device is activated and flow back when the piston section returns to its position shown in Figure 11. In this manner, the closing of the piston does not draw fluid back up the outlet section 148 when valve closes.

As shown in Figure 11A, the outlet section 148 is tied to the material 141 surrounding voids 149 by webs 147. The openings 146 extend through the webs 147 to provide fluid communication between the interior of the housing 132, including channels 143 and 145, and the outlet section 148.

The needlefree connector 150 shown in Figure 12 is much like the connector 130 except that the flow path through the body of the connector is

through a helical groove 154 made in the side wall of housing 152, rather than thc longitudinal flow paths 143 shown in Figure 11. The top section of housing 152 also includes some helical vents 157. These vents do not extend all the way to the top of the housing. However, they do extend to the shoulder that is used to make the valve member inside the housing. The vents allow the piston section to close most of the way without the wiper seal causing reflux. The vents are smaller in their outer diameter than the top of the biasing section so that thc main scal can still be made.

The connector 170 shown in Figure 13 is somewhat different in that the biasing section 175 is molded as if it were two zigzag members 177 and 178. Each is as thick as half the diameter, and as wide as the diameter, of the inside of the housing. The mold tool that forms this part has matting surfaces that contact each other over most of the longitudinal plane through a diameter of the connector. However, each of these tool surfaces has a zigzag pattern cut into it, but the zigzags are opposite to one another. Thus when the tool closes up, the corner portions of the cuts are opposite flat steel, while the central sections of the cuts intersect with one another. The resulting molded biasing section thus has central areas in which the two zigzag pieces connect to one another. This design has a flow path that goes back and forth across the width of the housing, through the spaces in between the members 177 and 178, as it flows downwardly. Also, longitudinal flow path channels 184 and circumferential flow channel 183are provided in the side wall of the housing 186 so that fluid can flow into an opening 180 formed in the outlet section 182. Again, this part can be molded in a two shot molding process, where the outlet section 182 is molded first and the piston section and biasing section 175 are overmolded onto it. Figure 13 shows a mechanical lock between the thermosetting material used to make the biasing section 175 and the thermoplastic used to make the outlet section 182.

Figure 14 shows how the needlefree connector of the present invention can be used as a bag port on an IV bag 200. The connector 210 has nearly the same configuration as connector 10, except that the base of the housing and outlet section are modified because they are sealed into the IV bag and do not need to be

connected to an IV line. As with other IV bags, a membrane seal 206 is provided on the bag, which may be punctured with a spike 207. The bag can thus be stored for a long time in a sterile condition until it is punctured. The spike is sized to form an interference fit with the walls 208 of the port initially sealed by membrane 206. The spike is then used to withdraw fluid from the IV bag. The connector 210 provides a port where a drug can be injected into the fluid within the bag 210.

The connector 210 can also be used in a large volume drug container which may be in the form of a bag that may contain hundreds of doses of drug. The needlefree connector 210 is then used as an access port to withdraw a single dose from the large volume container. The connector 210 may also be used as an access port on a diluent container, such as a bag that contains a saline solution.

In this regard, it should be appreciated that other embodiments of the connectors of the present invention could also be used as an IV bag port. It should also be noted that the needleless connector of the present invention can be used for other purposes, such as a vial adapter, to allow fluid to be aspirated from a vial without the use of a needle. Of course the internal components of the connector can also be used to make Y shaped connectors (see Figures 28 and 29) by using a housing having another inlet.

A variety of flow control members that can be used to make other embodiments of needlefree connectors of the present invention are shown in Figures 15-20. These flow control members can be assembled with a housing such as housing 20 to make a needlefree connector, or can be used to make y-site needlefree connectors.

The flow control member 240 shown in Figure 15 differs from flow control member 40 in three main ways. First, the opening 246 in piston section 242 is V shaped, as opposed to wedge shaped. Second, the outside of the biasing section 244 has a pointed configuration in the flights of the helical path. Third, the inside surface of the hollow portion 248 is not smooth, but rather also has a helical groove in it. This is thought to help the biasing section deform more uniformly when depressed. The center core pin used to make the hollow portion 248 will still be able to be withdrawn because of the resiliency of the material used to make

biasing section 244. Alternatively, it can be twisted out to follow the geometry of the internal helix.

Flow control member 250, shown in Figure 16, is similar to flow control member 240, except the outside of biasing section 254 does not have a pointed configuration. However, it still provides a helical flow path.

Flow control member 260, shown in Figure 17, has a thin-walled biasing section 264, with a helical pattern both on the inside and outside, such that the thickness of the wall of the biasing section is generally uniform.

Figure 18 shows a flow control member 270 that is different in that it has a flow path through the piston section. An opening 276 in the piston section 272 interconnects with the central hollow section 278 in the biasing section 274. The piston section 272 may have an elliptical top section, with the opening 276 being closed until the piston section 272 is depressed to a point within a housing having a larger diameter, at which point it can open so that flow can go through the piston section.

Flow control member 280, shown in Figure 19, is similar to flow control member 270 in having an opening 286 providing a flow path through the piston 282. However, the hollow central section 288 is formed in an undulating pattern to match the outside of the biasing section 284, thus creating a "bellows" design that can collapse as the piston 282 is depressed.

Figure 20 shows another embodiment of a flow control member 290 that is designed to collapse in a different manner since the biasing section 294 has holes axially through its center, as well as recesses 298 in its sides. The piston section 292 can have a wedge shaped opening, or the entire piston section can cock to one side as it is depressed and the biasing section buckles unevenly. In either event, the flow of fluid then goes around the outside of biasing section 294 until it can enter openings 297. The housing used with flow control member 290 will preferably have an internal threaded section such as section 35 in connector 10 (Figure 5).

Another two shot flow control member with quite a different design is used in needlefree connector 320 shown in Figure 21. In this embodiment, the biasing

section and piston section are combined in a single preslit septum valve 324. The housing 330 has a top section 331 that includes an annular ridge 332.

An inlet member 340 includes outside threads 344 to form a luer lock, and an inside shape that allows it to fit against the annular ridge 332. The inlet member 340 also includes an internal flange 346 to help secure the valve 324 to the inlet member 340. The inlet member 340 is molded first out of a thermoplastic material. The preslit septum valve 324 is overmolded inside of the inlet member, using a resilient material. The valve 324 has a slit 326 made in it either as part of the molding operation or afterwards. The combined pre-slit septum valve and inlet member is then sonically welded to the top 331 of the housing 330 to make the connector 320. The inlet member 340 preferably has a luer taper surface on its inside, which allows for a luer slip connection with a syringe tip. When the syringe tip is inserted into connector 320, the septum opens and the valve deforms inwardly, but is prevented from coming apart from the inlet member 340 because section 328 is captured between the inlet member 340 and the top 331 of the housing 330.

Another embodiment of a needlefree connector 350 is shown in Figures 26 and 27. This connector 350 uses a flow control member with a biasing section 360 which is solid in its center section and has a helical shape, much like the combined biasing and piston sections shown in Figure 9. The housing 370 can be configured just like housing 20. The outlet section 372 and openings 376 are just like outlet sections 70 and openings 76, respectively. The helical shape of the biasing section creates a helical flow path 374 within the housing.

The piston section or member 352 is similar to piston section 92, in that it has a wedged shape opening 356 in the top of the piston member. In addition, however, the piston member 352 further includes a radial flow channel 358 beneath the wedge shaped opening 356. As shown in Figure 26, the flow channel 358 is wider in its cross-section than the opening 356 in the top of the piston member 352. Thus, even when the piston member 352 is forced into a round inlet channel in the housing 370, which causes the wedge shaped opening 356 to close, the flow channel 358 underneath is still partly open. As seen in Figure 27, the

wedge shaped opening 356 extends radially to one side of the piston member from a point which is between the centerline of the piston member and the opposite side of the piston member. The flow channel 358 extends from an even more distant point to the outside of the piston member 352. This flow channel 358 has been found to improve flow through the connector 350 when a syringe tip depresses the piston and biasing sections.

Two Y-site needlefree connectors 380 and 390 are shown in Figures 28 and 29, respectively. Both connectors are very similar, and use the same biasing and piston sections as in connector 350. The two connectors differ in the piece in which the secondary inlet is provided. In connector 380 a secondary inlet 382 is formed in the housing 384. The outlet section 386, biasing section 385 and piston section 383 are formed by a two shot molding process. The secondary inlet 382 is formed in a separate leg of the housing 384 than that which is used to house the biasing and piston sections. The housing 384 may be molded as one monolithic part with two legs, as shown, or it may be made from different parts that are then welded together. The housing 384 and outlet section 386 may be connected together with solvent welding or other well known techniques.

The connector 390 has the secondary inlet 392 formed in the outlet section 386. The housing 394 is just the same as housing 20. The outlet section 386 is sonically welded to housing 394 just as housing 20 and outlet section 70 are welded together.

The wedge shaped openings 387 and 397 in the top of the respective piston sections 383 and 393 are shown closed in Figures 28 and 29. However, the flow channels 389 and 399 underneath the openings still have a hollow section as shown because they are wider in cross-section than the wedge shaped opening, and therefore do not close up all the way when the elliptical piston section is forced into the inlet of the housing.

In addition to the fact that the preferred connector may be assembled from only two parts, and thus have a lower manufacturing cost, the connector can also be made with higher quality control because of its fewer parts. Some of the functional requirements that are met by the preferred embodiments of the

invention are as follows. In addition to being low cost becausc of thc two part construction, the preferred connectors have an internal priming volume of less than 0.3 ml, more preferably less than 0.1 ml. After a flush procedure using 1.5ml of saline solution, the residual fluid in the connector should be less than 10% of the priming volume, preferably less than 2% of the priming volume. The preferred connectors have a flow rate, measurcd at 39" water head pressure, of greater than 100 ml/min., more preferably greater than 140 ml/min. The connectors can preferably be activated at least 100 times, and more preferably at least 200 times, and retain their other ability to reseal. In this manner one connector can be used on a patient that may need a large number of injections each day for several days.

The preferred connectors can withstand an internal pressure of at least 100 psi, and more preferably at least 300 psi, and a negative pressure of at least 12.5 psi and more preferably at least 14 psi. The wiper seal on the preferred connection will be able to prevent bacterial ingress for at least 24 hours, and more preferably at least 96 hours. Preferably the top wiper seal, in addition to preventing bacterial ingress, can withstand a pressure of 2 psi. The preferred connectors will have luer tapers on both the male and female connections, and be compatible with components that meet ISO 594-2 and ISO 494-2 standards, meaning that the connector male and female connections have the same diameter and 6% taper angle, but not necessarily the same length, as the ISO standards. However, they will preferably still provide contact over at least 0.1 inches of length, but not necessarily the 0.25 inch length contact of a standard luer taper. The preferred connectors are luer slip as well as luer lock compatible.

The amount of biasing force provided by the biasing member will preferably be at least 0.2 lbs, and more preferably at least 0.5 lbs, but will produce an activation force of less than 3.5 lbs, and more preferably less than 2.5 lbs. The preferred connectors have less than 30% flow reduction, and preferably less than 10% flow reduction, after 100 activations. The preferred connectors have a return time of less than 1 second, more preferably less than 0.5 seconds.

The preferred connectors will be made from materials that are compatible with a full range of fluids and antiseptics that are likely to come in contact with the connectors, such as high dextrose fluids, blood plasma, lipid emulsions, taxol and other chemotherapy drugs, and providone iodine, chlorhexidine and isopropyl alcohol antiseptics. The connectors will also preferably be compatible with various other medical devices, such as IV pumps, as well as gravity infusion, vacuum containers, jet injectors, IV sets and can withstand MRI fields. The preferred connectors can be sterilized by electron beam, steam, gamma radiation and ethyl oxide gas.

As will be appreciated, making a device such as the preferred embodiment of the invention that meets all of the above requirements, can be made with higher quality control, and can still be made at a low cost, is a considerable achievement. In addition, the preferred device is small, less than 1.3 inches, and preferably less than 1 inch in length.

It should be appreciated that the apparatus and methods of the present invention are capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above. For example, the central portion of the biasing section 60 could have a small diameter central hollow area, have a different pitch in the helical groove, be longer or shorter, etc. Also, rather than using a sonic or solvent weld to connect the housing with the flow control member, a snap-lock feature could be used. If this type of assembly were used, the housing could remain in its mold base and the separately molded flow control member could be inserted in an in-mold assembly operation, rather than the parts each being ejected from their mold base and assembled in a separate operation. The invention may be embodied in other forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WE CLAIM

1. A needlefree connector comprising:

   a) a housing having an inlet and an inlet channel; and

   b) a combination outlet, biasing and piston member having

      i) a piston section moveable between a closed position in which the piston section is in the inlet channel and an open position in which thc piston scction is inside the housing below the inlet channel but allows fluid to flow through the inlet channel,

      ii) a biasing section connected to the piston section that normally biases the piston section into the inlet channel; and

      iii) an outlet section interlocked to the biasing section and having an outlet fitting in fluid communication with the insidc of the housing; wherein the piston scction, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing to make the needlefree connector.

2. The needlefree connector of claim 1 wherein the inlet channel comprises a female luer taper.

3. The needlefree connector of claim 1 wherein the piston section in its closed position seals the inlet channel against airborne bacteria.

4. The needlefree connector of claim 1 wherein the combination outlet, biasing and piston member comprises thermoplastic material and resilient material.

5. The needlefree connector of claim 4 wherein the resilient material is overmolded onto the thermoplastic material.

6. The needlefree connector of claim 1 wherein the piston section in its closed position is either flush with or extends out of the housing inlet.

7. The needlefree connector of claim 1 wherein the biasing section is made from resilient material.

8. The needlefree connector of claim 7 wherein the resilient material of the biasing section has a Shore A durometer of between about 30 and 90.

9. The needlefree connector of claim 1 wherein the biasing section has a solid central section.

10. The needlefree connector of claim 4 wherein the resilient material is a resilient thermosetting material.

11. The needlefree connector of claim 1 wherein the biasing section is generally hollow.

12. The needlefree connector of claim 1 wherein the biasing section has a helical flow channel around its center portion.

13. The needlefree connector of claim 12 wherein the helical flow channel has a cross-sectional width of about 0.020 inches when the piston section is in its open position.

14. The needlefree connector of claim 1 wherein the piston section comprises a normally elliptical top portion with a wedge shaped opening therein.

15. The needlefree connector of claim 14 wherein the housing inlet is round and the piston member is deformable such that when the piston section is in its closed position, the top portion is forced into a round shape and the wedge shaped opening is closed.

16. The needlefree connector of claim 15 wherein the piston section further comprises a radial flow channel beneath the wedge shaped opening.

17. The needlefree connector of claim 1 wherein the housing comprises a generally smooth cylindrical wall surrounding the biasing section.

18. The needlefree connector of claim 17 wherein the housing further comprises an internal threaded section adjacent the connection between the biasing section and the outlet section.

19. The needlefree connector of claim 1 wherein the outlet section forms a closure to the housing, thus directing flow through the housing to pass through the outlet fitting.

20. The needlefree connector of claim 19 wherein the outlet section has a flange sonically welded to a recess within the housing to form said closure.

21. The needlefree connector of claim 7 wherein the resilient material of the biasing section has a Shore A durometer of between about 50 and about 80.

22. The needlefree connector of claim 1 where in the piston section includes a wiper seal.

23. The needlefree connector of claim 1 wherein the piston section and biasing section are formed as one monolithic piece.

24. The needlefree connector of claim 23 wherein the monolithic piece is overmolded onto the outlet section to provide the combination outlet, biasing and piston member.

25. A needlefree connector comprising:

a) a housing; and

b) a flow control member, the flow control member comprising thermoplastic material and resilient thermosetting material overmolded onto the thermoplastic material.

26. The needlefree connector of claim 25 wherein the flow control member is made in a two-shot molding process.

27. The needlefree connector of claim 25 wherein the flow control member comprises a piston section, a biasing section and an outlet section, the

piston and biasing section being made from the resilient thermosetting material and the outlet section being made from the thermoplastic material.

28. The needlefree connector of claim 27 wherein the housing comprises an inlet channel and the biasing section normally biases the piston section to close the inlet channel.

29. The needlefree connector of claim 28 wherein the biasing section provides a force of between about 0.2 lbs and about 3.5 lbs.

30. A flow control member for use in a needlefree connector, the flow control member comprising:

a) a outlet section formed of thermoplastic material; and

b) a combined biasing section and piston section formed from resilient material, the biasing section being overmolded onto the outlet section.

31. The flow control member of claim 30 wherein the resilient material comprises thermosetting material.

32. The flow control member of claim 31 wherein the thermosetting material comprises silicone.

33. The flow control member of claim 30 wherein the resilient material comprises thermoplastic elastomer.

34. The flow control member of claim 30 wherein the biasing section has a solid central portion and is shaped in a helix.

35. The flow control member of claim 30 wherein the biasing section has a central hollow portion and a helical flow channel formed in its outer surface.

36. The flow control member of claim 30 wherein the piston section comprises a normally elliptical top portion with a wedge shaped opening therein.

37. The flow control member of claim 30 wherein the piston section comprises an opening in the top thereof; and a flow channel beneath and connected to the opening and extending radially to the outside of the piston section, the flow channel having a cross-sectional area larger than that of the opening in the top of the piston.

38. The flow control member of claim 30 wherein the piston section comprises a normally elliptical top portion with a V-shaped opening across a minor axis of the ellipse.

39. The flow control member of claim 30 wherein the outlet section is mechanical interlocked to the biasing section.

40. A needlefree connector comprising:

a) a housing having a round inlet, a tapered inlet channel that narrows inwardly from the inlet, a main body portion and a base opposite the inlet;

b) a piston member inside the housing; and

c) a biasing member inside the housing normally biasing the piston member to close the inlet;

d) wherein the piston member comprises a resilient material with a top having a generally elliptical shape and an opening that is closed when the top of the piston is forced into said round inlet opening but which allows flow through the opening to the outside of the piston member when the piston member is forced downwardly against the biasing force and out of the tapered inlet channel.

41. The needlefree connector of claim 40 wherein the opening in the piston member is wedge-shaped.

42. The needlefree connector of claim 40 wherein the opening comprises an opening in the top surface of the piston member and a flow channel underneath the opening in the top which is wider in cross-section than the opening in the top.

43. The needlefree connector of claim 40 wherein the biasing member comprises a resilient member formed monolithically with the piston member.

44. The needlefree connector of claim 43 wherein the biasing member has a hollow central portion, but the opening in the piston does not interconnect with the hollow central portion.

45. The needlefree connector of claim 40 wherein the piston member includes a wiper seal capable of preventing airborn bacterial ingress while the piston is in a closed position.

46. The needlefree connector of claim 45 wherein the wiper seal can also withstand a pressure of at least 2 psi.

47. The needlefree connector of claim 40 wherein the piston has a top surface that extends above the inlet.

48. The needlefree connector of claim 47 wherein the top surface of the piston member is slanted and expends above the inlet on only one side of the connector.

49. The needlefree connector of claim 41 wherein the wedge shaped opening extends radially to one side of the piston member from a point which is between the centerline of the piston member and the opposite side of the piston member.

50. A method of making a needlefree connector comprising:

a) forming a housing having an inlet and a base;

b) forming a flow control member by

i) molding thermoplastic material to form an outlet member and

ii) overmolding resilient material onto the outlet member, the resilient material forming a piston section and a biasing section;

c) inserting the flow control member into the housing such that the piston section is adjacent to the inlet; and

d) securing the outlet member into the base of the housing.

51. The method of claim 50 wherein the outlet member is sonically welded into the base of the housing.

52. The method of claim 50 wherein the thermoplastic material is injected in a molten state into a mold having a base section and a first top section and allowed to solidify.

53. The method of claim 52 wherein after the thermoplastic material is allowed to solidify, the first top section of the mold is removed, the solidified thermoplastic material remains in the base section of the mold and a second top section mold is placed over the base section of the mold, the second top section having a cavity for molding the resilient material.

54. The method of claim 53 wherein the resilient material is a silicone thermosetting material made by mixing silicone part A and silicone part B together and injecting the mixture into the cavity in the second top section.

55. The method of claim 54 wherein the mixture is injected at a pressure of between about 100 psi and about 900 psi, and at a temperature of between about 50°F and about 100°F.

56. The method of claim 52 wherein the thermoplastic material is injected at a temperature of between about 300°F and about 800°F, and at a pressure of between about 500 psi and about 2000 psi.

57. The method of claim 54 wherein the second top mold section is at a temperature of between about 250°F and about 400°F when the mixture is injected.

58. The method of claim 52 wherein the mold basc section is at a temperature of between about 50°F and about 300°F when the thermoplastic material is injected.

59. The method of claim 50 wherein the thermoplastic material is selected from the group consisting of polycarbonates, polysulfones, nylons and acrylics.

60. A method of making a needlefree connector comprising:

a) providing a first part comprising a monolithically formed housing;

b) providing a second part comprising a combination outlet section, biasing section and piston section;

c) constructing the needlefree connector by securing the second part within the first part, the connector being made only from the first and second parts.

61. A needlefree connector comprising:

a) a housing; and

b) a flow control member, the flow control member comprising a thermoplastic outlet section and a resilient material overmolded onto the thermoplastic material.

62. The needlefree connector of claim 61 wherein the housing includes threads for a luer lock fitting in the area surrounding the inlet channel.

63. The needlefree connector of claim 61 wherein the housing comprises a base with threads for forming a luer lock.

64. The needlefree connector of claim 1 wherein the housing comprises an internal sealing surface and the piston section seals against the sealing surface to prevent backflow through the connector when the piston section is in its closed position.

65. The needlefree connector of claim 22 wherein the wiper seal closes the inlet against airborn bacteria when the piston section is in the closed position.

66. A needlefree connector comprising:

a) a housing having an inlet, a base, and a main body portion having a generally cylindrical inside surface between the inlet and the base;

b) a valve member actuatable between an open position and a closed position, wherein in the closed position the valve member prevents flow between the inlet and the outlet;

c) a central body within the main body portion of the housing, the central body having a helical shape on its outer surface, the central body fitting against the inside of the cylindrical surface when the valve member is in its open position;

d) the helical shape defining a helical flow path through the main body portion of the housing when the valve member is in an open position.

67. The needlefree connector of claim 66 wherein the housing further comprises a tapered inlet channel having a luer taper for engaging with a syringe tip having a luer taper.

68. The needlefree connector of claim 66 wherein the valve member is formed as part of a piston section of a combined piston section and biasing section.

69. The needlefree connector of claim 68 wherein the central body forms part of the biasing section.

70. The needlefree connector of claim 68 wherein the combined piston and biasing section comprises resilient material and is overmolded onto an outlet section comprising thermoplastic material, which in turn is attached to the base of the housing.

71. The flow control member of claim 30 wherein thc top portion of the piston has a V-shaped opening therein.

72. The needlefree connector of claim 43 wherein the biasing member has a solid central portion.

73. The needlefree connector of claim 1 wherein the needlefree connector is in the form of a Y-shape connector, and comprises a secondary inlet.

74. The needlefree connector of claim 73 wherein the secondary inlet is formed in the housing.

75. The needlefree connector of claim 73 wherein the secondary inlet is formed in the outlet section.

76. An IV bag having a port comprising a needlefree connector as recited in claim 1.

ABSTRACT OF THE DISCLOSURE

A needlefree connector includes a housing having an inlet and an inlet channel; and a flow control member comprising a combination outlet, biasing and piston member. The flow control member includes a piston section moveable between a closed position in which the piston section is in the inlet channel and an open position in which the piston section is inside the housing below the inlet channel but allows fluid to flow through the inlet channel; a biasing section connected to the piston section that normally biases the piston section into the inlet channel; and an outlet section connected to the biasing section having an outlet fitting in fluid communication with the inside of the housing. The piston section, biasing section and outlet section are connected together such that they can be handled as one piece when assembled with the housing to make the needlefree connector. The connector can be configured as a Y-site connector, or used on other devices, such as an IV bag.

Patent Application for: Needlefree Connector And
Method Of Making Same
Inventor(s): Ronald J. Kay and Ricky R. Ruschke
Attorney Docket No. 396/455
Sheet 1/10

FIG. 1

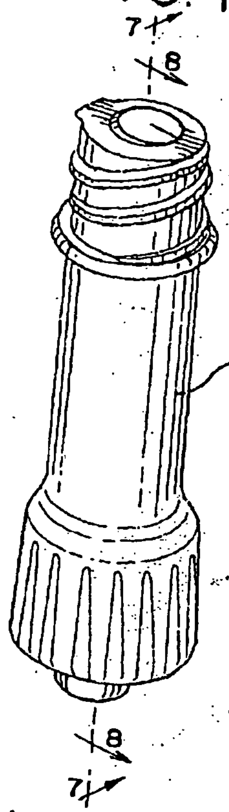

FIG. 4

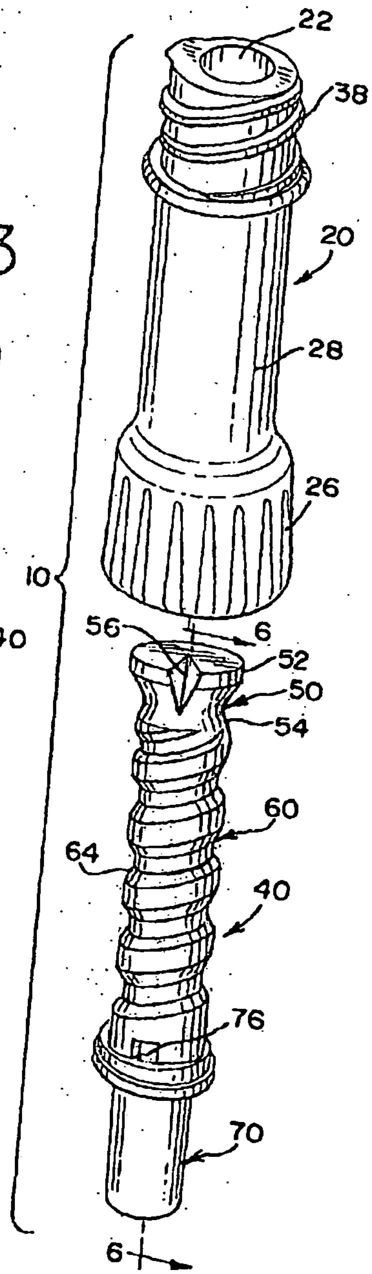

FIG. 3

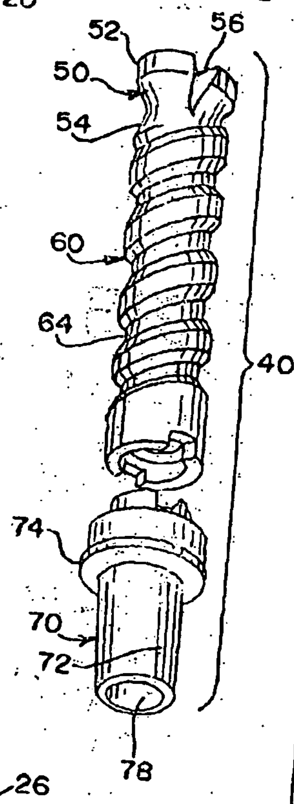

FIG. 2

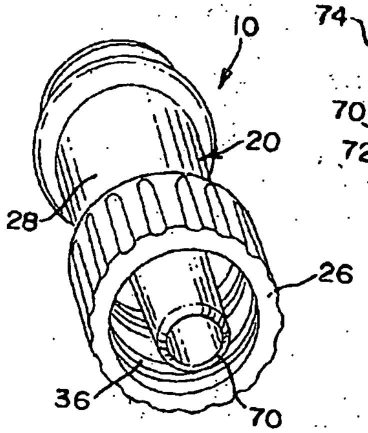

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FIG. 7

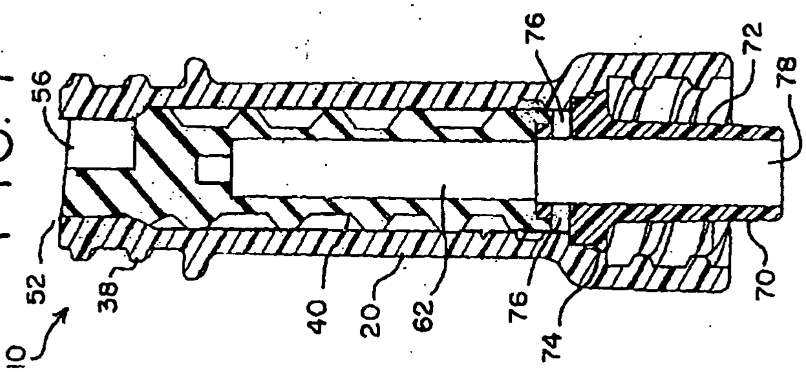

FIG. 6

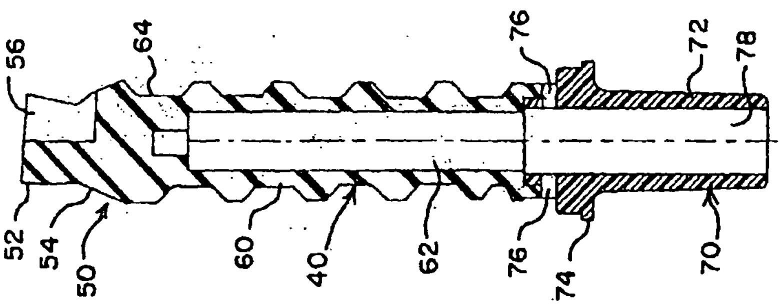

FIG. 5

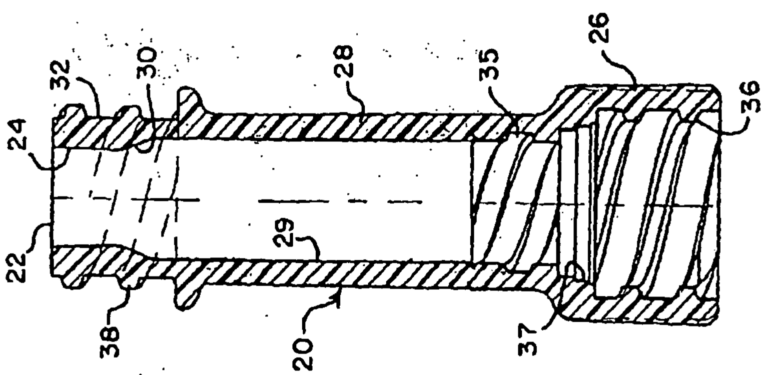

FIG. 8

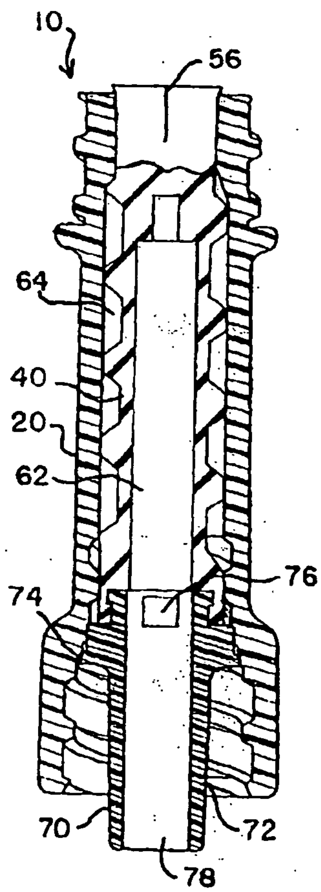

FIG. 8A

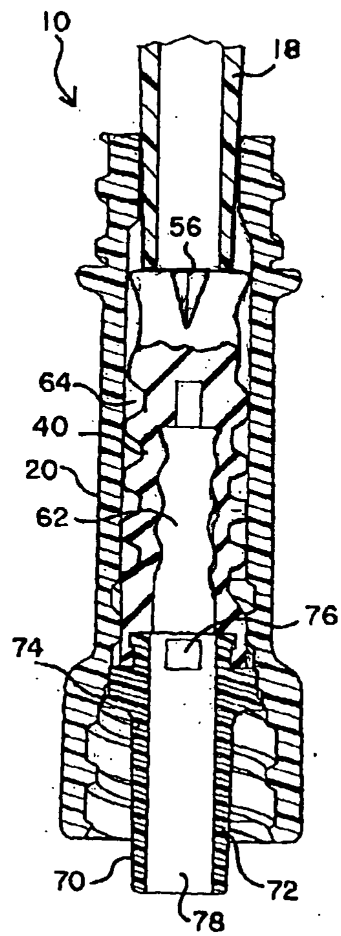

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FIG. 11

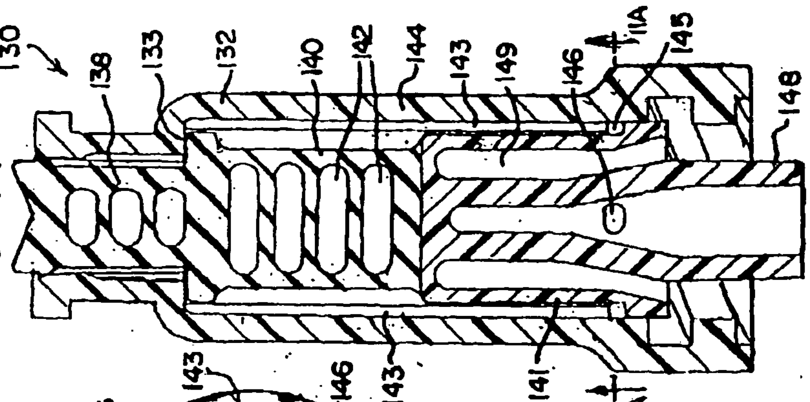

FIG. 11A

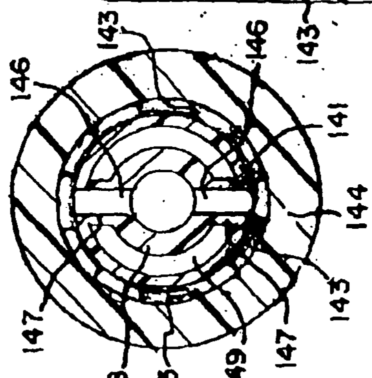

FIG. 10

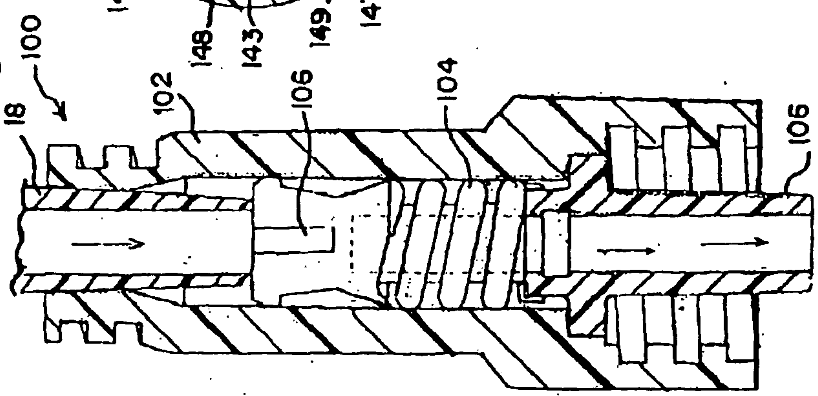

FIG. 9

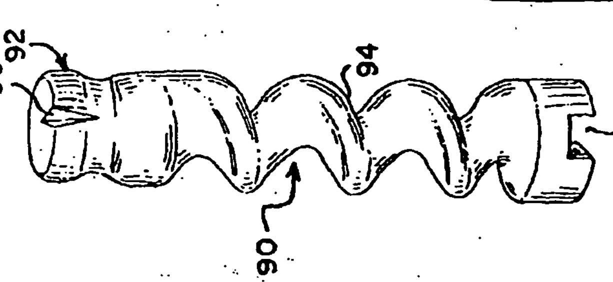

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FIG. 14

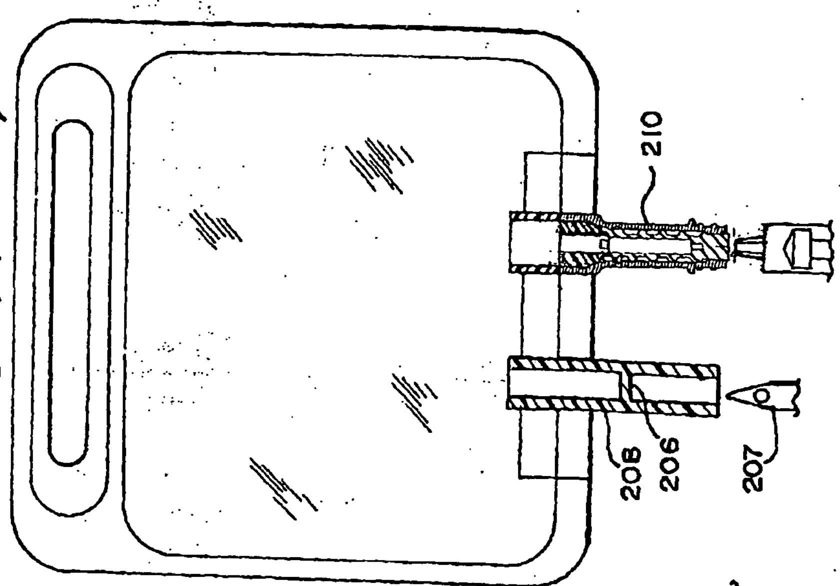


FIG. 13

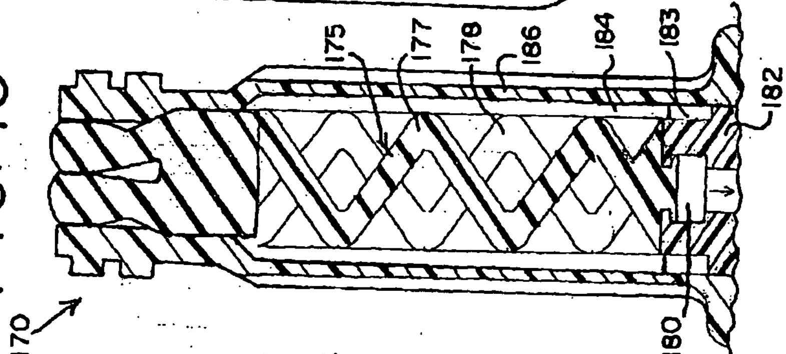


FIG. 12

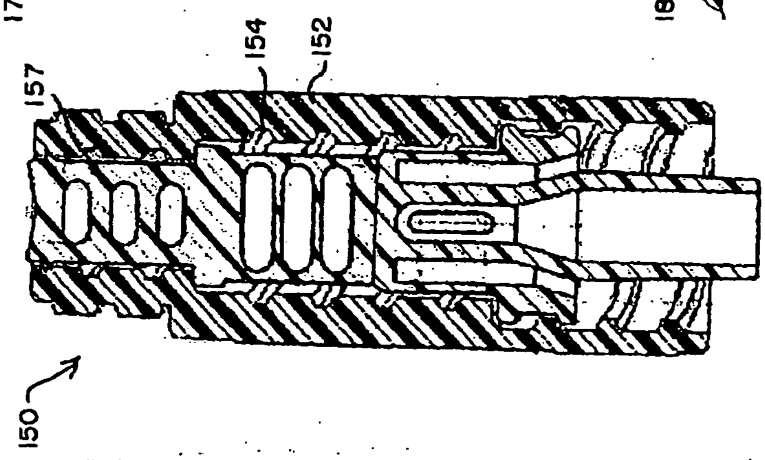


FIG.15

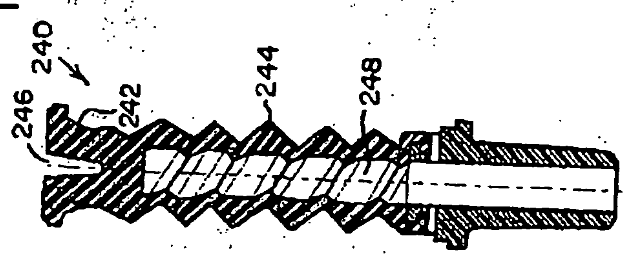


FIG.16

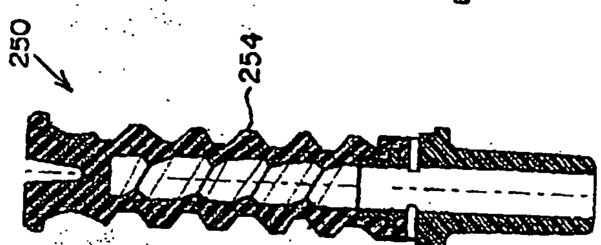


FIG.17

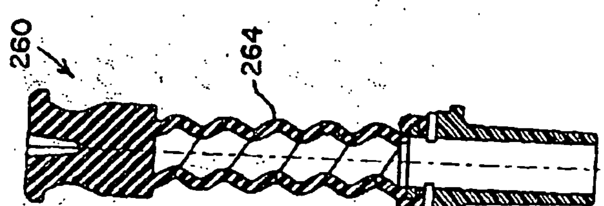


FIG.18

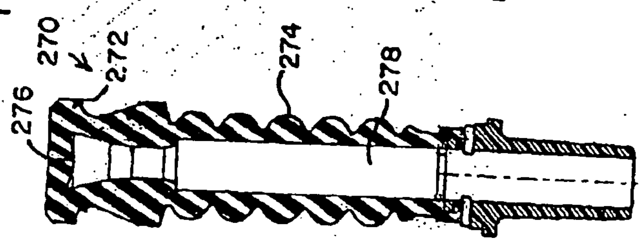


FIG. 19

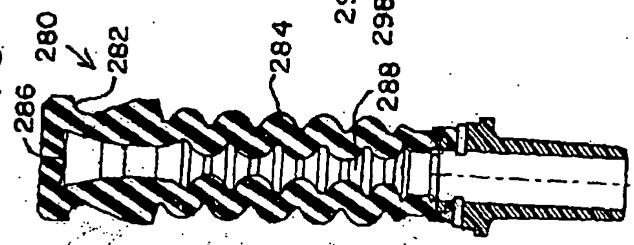


FIG.20

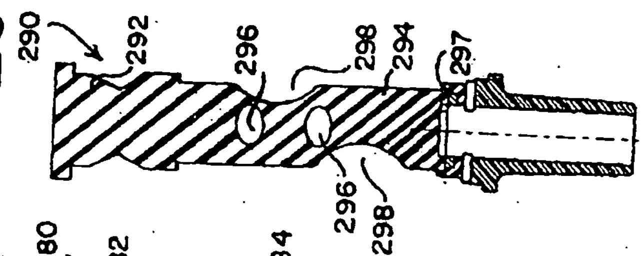


FIG. 21

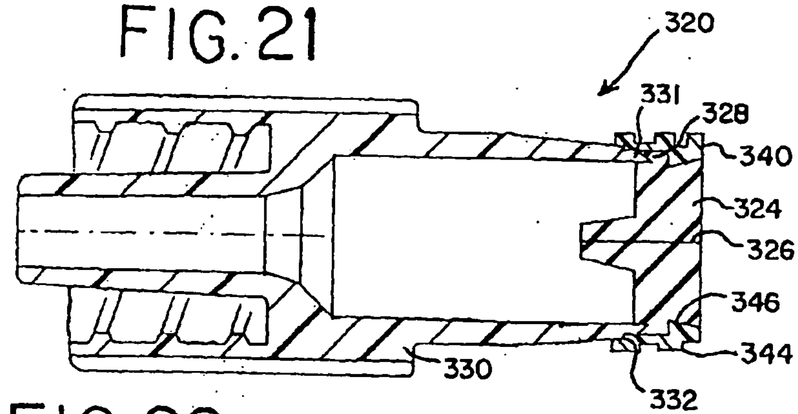


FIG. 22

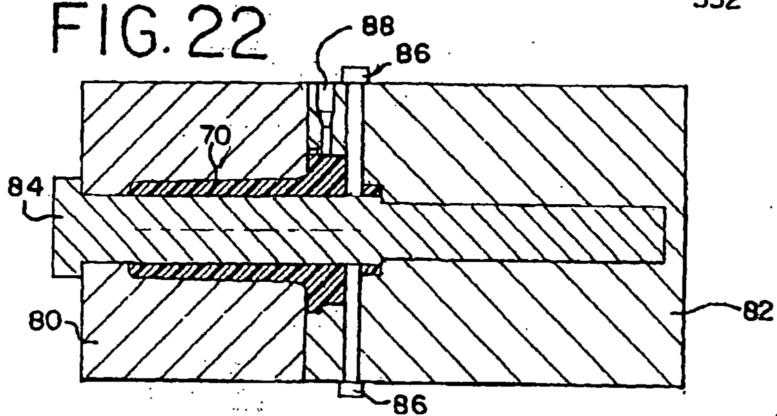


FIG. 23A

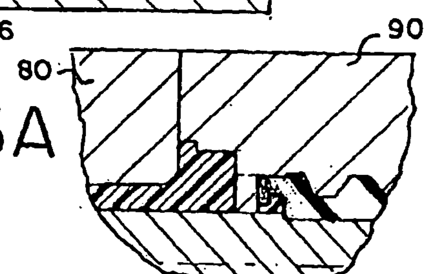
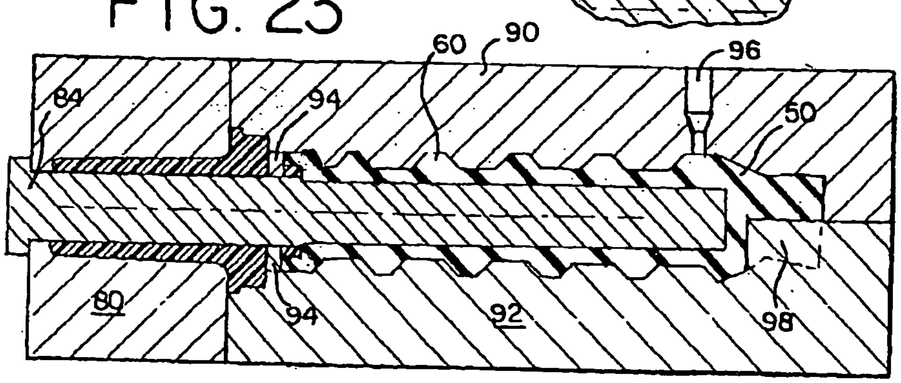


FIG. 23



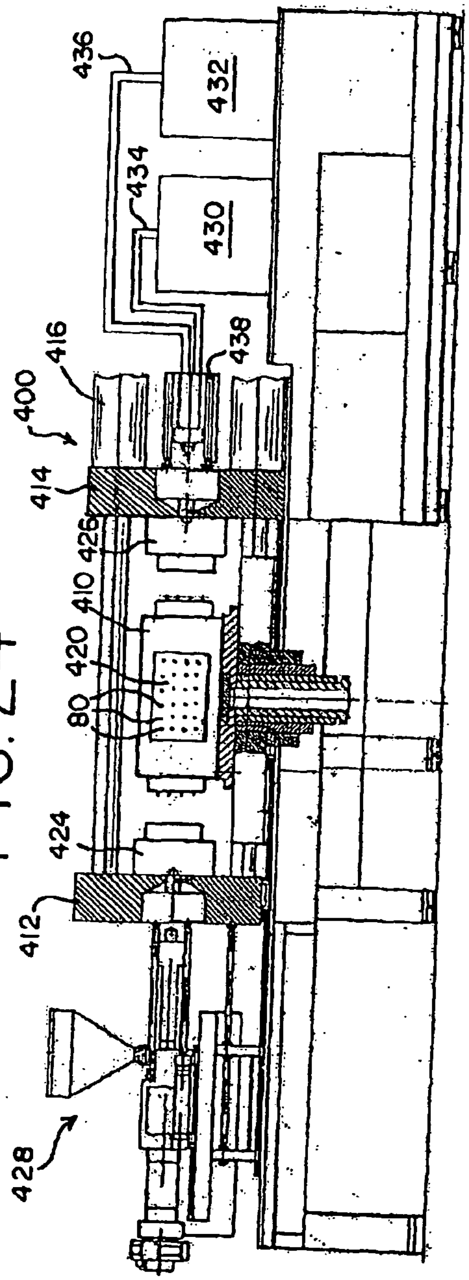


FIG. 24

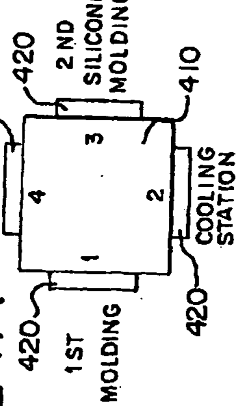


FIG. 24A

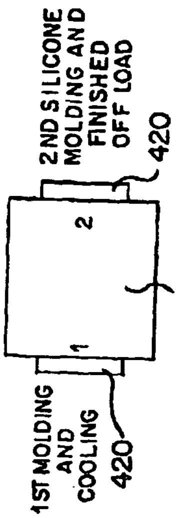


FIG. 24B

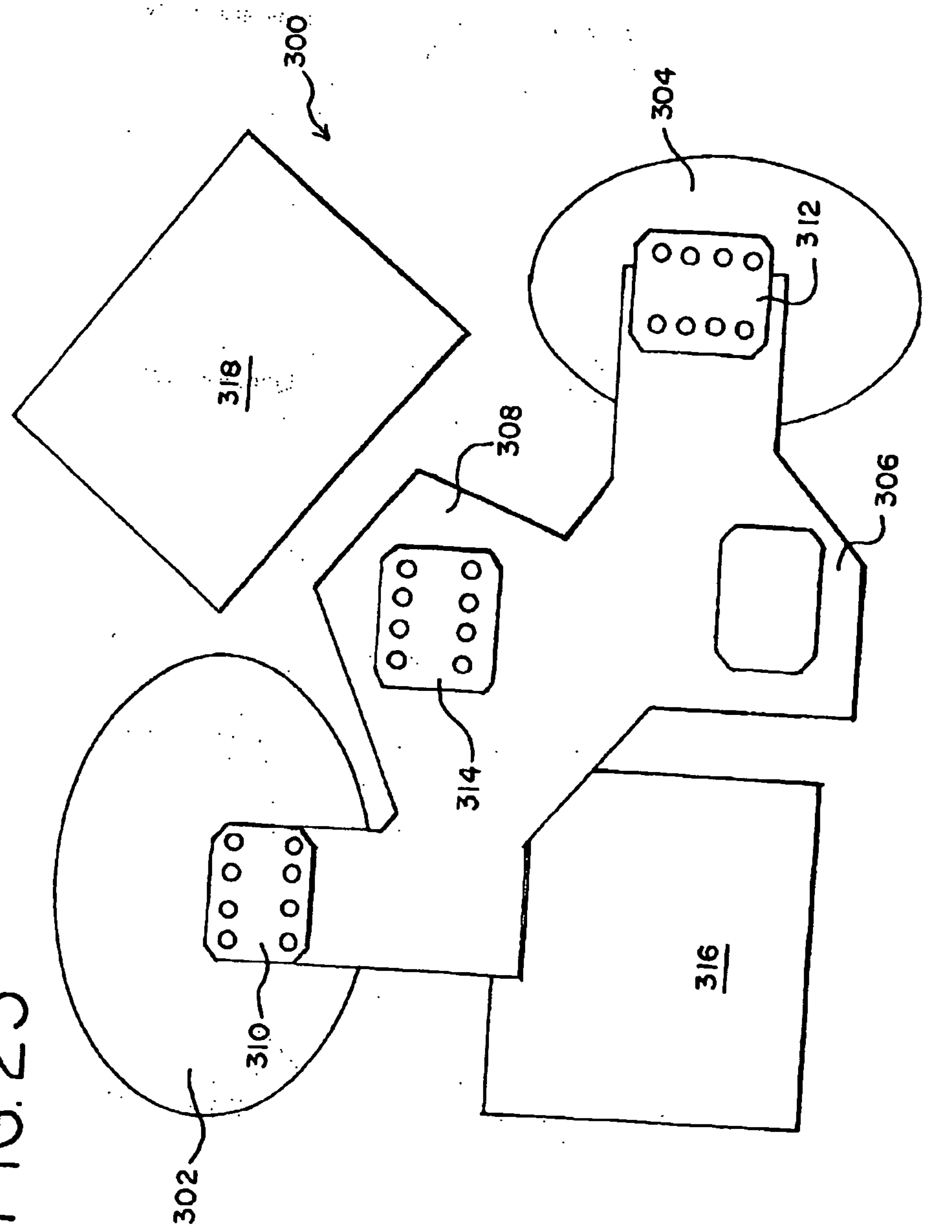


FIG. 25

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